K121315
1 of 2

15 Dart Road
Newnan, GA 30265
t: 770-254-4400
www.stryker.com

stryker

Craniomaxillofacial

510(k) Summary

NOV 1 2012

Date Prepared:	October 5, 2012
Sponsor/Manufacturer:	Howmedica Osteonics Corp. 15 Dart Road Newnan, GA 30265 USA
Distributor:	Stryker Craniomaxillofacial 750 Trade Centre Way, Suite 200 Portage, MI 49002 USA
510(k) Contact Person:	Stephanie Fullard Manager, Regulatory Affairs Howmedica Osteonics Corp. 15 Dart Road Newnan, GA 30265 Phone: (770) 254-4423 Fax: (678) 423-1437 stephanie.fullard@stryker.com
Proprietary Name:	Stryker CMF MEDPOR Customized Implant
Common Name:	Porous High Density Polyethylene (HDPE) Implant
Classification Name and Reference:	Prosthesis, Chin, Internal, 21 CFR §878.3550
Proposed Regulatory Class:	Class II
Product Codes:	FWP
Predicate Devices:	MEDPOR Customized Surgical Implant (K083621) Stryker Patient Specific Polymer Implant (K103010) Stryker Patient Specific Polymer Implant (K111065)

Device Description:
The Stryker CMF MEDPOR Customized Implant is sold as a kit of two identical implants plus one host bone model. The customized craniofacial implant is molded from porous high density polyethylene (HDPE) to the specific dimensions indicated by the surgeon via submission of CT scans. The porous HDPE Implant is fixed into place using compatible Stryker screws.

Intended Use / Indications for Use:
The Stryker CMF MEDPOR Customized Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

Technological Characteristics:
The subject device Stryker CMF MEDPOR Customized Implant is a modification of the previously cleared MEDPOR Customized Surgical Implant. The subject device will now be sold as a kit with two sterile implants and a host bone model like the predicate Stryker Patient Specific Polymer Implants. It was determined that none of the modifications impact safety and effectiveness.

Performance Data:
The Stryker CMF MEDPOR Customized Implant was verified and validated according to Stryker procedures for product design and development. Bench testing was performed to demonstrate equivalence of the subject device to the predicate devices. Biocompatibility testing according to ISO 10993-1 was demonstrated by clearance of the predicate devices and in vitro cytoxoxicity testing was performed per ISO 10993-5. Sterilization validations were performed in accordance with ISO 11135, 11137 and 11737; EO residuals testing per ISO 10993-7 and pyrogenicity testing via LAL according to AAMI ST72. Validation of the Virtual Implant Design Process (VIDP) which mirrors the original VIDP Validation (cleared under K103010). Packaging validations and ship testing were performed in accordance with ISO 11607, ASTM F1886, F1929, D642 and F88 to ensure that sterility is maintained throughout the product's labeled shelf life.

No new clinical testing was required.

Substantial Equivalence:
The Stryker CMF MEDPOR Customized Implant is substantially equivalent to the predicate devices identified above in terms of indications, materials, design and operational principles. The Stryker CMF MEDPOR Customized Implant has been verified and validated according to Stryker procedures for product design and development. The information presented in this submission supports substantial equivalence of the Stryker CMF MEDPOR Customized Implant to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 1 2012

Howmedica Osteonics, Corporation
% Ms. Stephanie Fullard
Manager, Regulatory Affairs
15 Dart Road
Newnan, Georgia 30265

Re: K121315
Trade/Device Name: Stryker® CMF MEDPOR Customized Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prosthesis
Regulatory Class: Class II
Product Code: FWP
Dated: October 05, 2012
Received: October 09, 2012

Dear Ms. Fullard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S
2012.11.01 15:37:19 -04'00'

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121315

Device Name: Stryker® CMF MEDPOR Customized Implant

Indications for Use:

The Stryker CMF MEDPOR Customized Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121315

Page 1 of 1